

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/909,311	07/19/2001	Heiner Max	Beiersdorf 733-KGB	9953
75	01/06/2004		EXAM	INER
Norris McLaughlin & Marcus PA			JIANG, SHAOJIA A	
220 East 42nd Street 30th Floor			ART UNIT	PAPER NUMBER
New York, NY 10017			1617	
			DATE MAILED: 01/06/2004	1

Please find below and/or attached an Office communication concerning this application or proceeding.

	Applicati n N .	Applicant(s)				
Advisory Action	09/909,311	MAX ET AL.				
Auvisory Action	Examin r	Art Unit				
	Shaojia A Jiang	1617				
The MAILING DATE of this communication appears n the cover sheet with the correspondenc address						
THE REPLY FILED 05 December 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.						
PERIOD FOR REPLY [check either a) or b)]						
a) The period for reply expires 3 months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
1. A Notice of Appeal was filed on Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.						
2. The proposed amendment(s) will not be entered because:						
(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);						
(b) ☐ they raise the issue of new matter (see Note below);						
(c) Ithey are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or						
(d) They present additional claims without canceling a corresponding number of finally rejected claims.						
NOTE: <u>see attachment</u> .						
3. Applicant's reply has overcome the following rejection(s):						
4. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).						
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: <u>See attachment</u> .						
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.						
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.						
The status of the claim(s) is (or will be) as follows:						
Claim(s) allowed: <u>none</u> .						
Claim(s) objected to: <u>none</u> .						
Claim(s) rejected: 24-38.						
Claim(s) withdrawn from consideration: none.						
8. ☐ The drawing correction filed on is a) ☐ appr	oved or b) disapproved by the	ne Examiner.				
9. Note the attached Information Disclosure Statemer	nt(s)(PTO-1449) Paper No(s)	·				
10. Other:						
	PRIM	DORE J. CRIARES IARY EXAMINER GROUP 1280 /6 00				

Advisory Action

This Office Action is a response to Applicant's proposed amendment and response <u>after FINAL</u> filed on December 5, 2003.

- 2. Applicant's pending claims 24-38 (previously presented) and proposed newly submitted claims 39-42 are not deemed to place the application in better form for appeals by materially reducing or simplifying the issues for appeal. More importantly Applicant's proposed amendment does not pleace the application in condition for allowance as further discussed below.
- 5. The rejection of Claims 24-26 and 28-29 made under 35 U.S.C. 102(b) as being anticipated by Sanchez et al. (5,296,472) for reasons of record stated in the Final Office Action dated August 26, 2003 is maintained.

The rejection of Claim 27 made under 35 U.S.C. 103(a) as being unpatentable over the same reference by Sanchez et al. (5,296,472) for reasons of record stated in the Final Office Action dated August 26, 2003 is maintained.

The rejection of 30-34 and claims 35-38 made under 35 U.S.C. 103(a) as being unpatentable over the same reference by Sanchez et al. (5,296,472) for reasons of record stated in the Final Office Action dated August 26, 2003 is maintained.

Applicant's remarks and Exhibit filed December 5, 2003 with respect to the rejections of record, have been fully considered but are <u>unpersuasive</u> for reasons of record stated in the Final Office Action dated August 26, 2003.

Art Unit: 1617

Applicant's arguments and Exhibit with respect to the examiner's position that the mechanism of action of a treatment has no bearing on the patentability of the claims and the inherency in the administration to skin and/or hair (topically) of cyclodextrins, are again not found convincing. As discussed in the previous Office Action, Sanchez et al. discloses methods for delipidation of skin and/or hair, or for controlling the excessive buildup of sebum or sebum production on mammalian skin or hair comprising topically applying to skin and/or hair an effective amount of a composition comprising a cyclodextrin component having one or more cyclodextrin. See abstract, col.1 lines 14-17 and 31-33, col.3 lines 13-14 and 61-65, and col.8-9 Example 3-5, in particular. Thus, the method of Sanchez et al. would be clearly useful in the inhibition of sebum production.

Secondly, as pointed out in the previous Office Action, most importantly, the mechanism of action of a treatment does not have a bearing on the patentability of the invention if the method steps are already known even though applicant has proposed or claimed the mechanism (e.g., reach the sebaceous glands and have the desired metabolic effects). Applicant's recitation of a new mechanism of action for the prior art method will not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps, i.e., applying to skin and/or hair. See *Ex parte Novitski*, 26 USPQ 2d 1389. Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by

virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. A chemical composition and its properties are inseparable.

Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed method administering the same product. The prior art teaches application to the skin of compositions containing the same components as instantly claimed, which would inherently reduces the production of sebum in skin and/or hair, as instantly claimed. Applicant has not provided any evidence of record to show that the prior art compositions do not exhibit the same properties as instantly claimed.

Therefore, Sanchez et al. anticipates Claims 24-26 and 28-29.

Applicant's arguments with respect to the rejection of claims 30-38 are not found persuasive. As discussed in the previous Office Action, Sanchez et al. clearly discloses that the effective amounts of cyclodextrin component broadly including α -, β -, γ cyclodextrins in the topical compositions therein are about 1-30% by weight within the instant claims. See col.2 lines 57-63 in particular. Therefore, one of ordinary skill in the art would have found it obvious to employ at least 30% weight of the particular known cyclodextrin, y-cyclodextrin, in Sanchez's compositions. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See In re Boesch, 205 USPQ 215 (CCPA 1980).

As pointed out in the Final rejection, the specification contains no clear and convincing evidence of nonobviousness or unexpected results for the claimed method herein over the prior art. In this regard, it is noted that the specification provides no sideby-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

For the above stated reasons, claims 27 and 30-38 are properly rejected under 35 U.S.C. 103(a). Therefore, said rejections are adhered to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-H Cum 1235.

S. A. Jiang, Ph.D. Patent Examiner, AU 1617 December 29, 2003

THEODORE J. CRIARES PRIMARY EXAMINER GROUP 1200 7600